MAR 1 2 2002

K012045

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510(k) SUMMARY of Safety and Effectiveness

Sponsor:	Highgate Orthopaedics One Walnut Street Boston, MA 02108
Proposed Proprietary Trade Name:	Highgate Curved Rod System
Device Description:	The Highgate Curved Rod System is available in titanium alloy (Ti6Al4V, ASTM F136) and includes rods and screws. Lateral and end screws are used to attach the rod to the thoracolumbar spine. Rods are offered in two curvatures and have circular openings accommodate the screws.
Indication/Intended Use:	The Highgate Curved Rod System is intended for unilateral screw fixation of the anterolateral thoracolumbar spine from T_6 to L_5. The Highgate Curved Rod System is intended to provide stabilization of a spinal segment as an adjunct to spinal fusion. Indications for the use of this device include spondylolisthesis (Grades 1 and 2), spinal stenosis, pseudarthrosis, failed fusion or degenerative disc disease (DDD) defined as back pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. The Highgate Curved Rod System is **not** intended for patients having severe spondylolisthesis (Grades 3 and 4), deformities or curvatures, tumor or trauma i.e. vertebral fracture.
Materials:	The Highgate Curved Rod System components are manufactured from titanium alloy (Ti6Al4V, ASTM F136).
Substantial Equivalence:	The Highgate Curved Rod System was determined to be substantially equivalent to several commercially available systems.
Performance Characteristics:	Static and fatigue mechanical testing were supplied in support of the Highgate Curved Rod System 510(k) premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2002

Highgate Orthopaedics
c/o Ms. Karen E. Warden, MEBE
Representative/Consultant
8202 Sherman Road
Chesterland, Ohio 44026-2141

Re: K012045
Highgate Curved Rod System
Regulation Number: 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: February 13, 2002
Received: February 20, 2002

Dear Ms. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K012045

Device Name: **Highgate Curved Rod System**

Indications for Use:

The Highgate Curved Rod System is intended for unilateral screw fixation of the anterolateral thoracolumbar spine from T_6 to L_5. The Highgate Curved Rod System is intended to provide stabilization of a spinal segment as an adjunct to spinal fusion. Indications for the use of this device include spondylolisthesis (Grades 1 and 2), spinal stenosis, pseudarthrosis, failed fusion or degenerative disc disease (DDD) defined as back pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. The Highgate Curved Rod System is **not** intended for patients having severe spondylolisthesis (Grades 3 and 4), deformities or curvatures, tumor or trauma i.e. vertebral fracture.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use_____ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

510(k) Number K012045